UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

File No.: 09 CV 2723 DWF/RLE

MINNESOTA PHARMACISTS ASSOCIATION, NATIONAL ASSOCIATION OF CHAIN DRUG STORES, NATIONAL COMMUNITY PHARMACISTS ASSOCIATION, MINNESOTA RETAILERS ASSOCIATION, MINNESOTA GROCERS ASSOCIATION, ASTRUP DRUG, INC., COBORN'S, INC., FALK'S PHARMACIES, INC., GENOA HEALTHCARE MINNESOTA, LLC, GOODRICH PHARMACY, INC., JT HOESCHEN, INC. d.b.a. ST. PAUL CORNER DRUG, SETZER PHARMACY, INC., THRIFTY DRUG STORES, INC., TRUMM DRUG, INC., ROBERT DIAZ, and M.B., a minor, and A.H. a minor, by and through their Legal Guardian, JAMES BRECH,

Plaintiffs,

v.

TIMOTHY PAWLENTY, not individually, but solely in his official capacity as Governor of the State of Minnesota, CAL LUDEMAN, not individually, but solely in his official capacity as Commissioner of the Minnesota Department of Human Services, BRIAN OSBERG, not Individually, but solely in his official capacity as Director of the Minnesota Medicaid Program, THE MINNESOTA DEPARTMENT OF HUMAN SERVICES,

Defendants.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

COME NOW the Minnesota Pharmacists Association ("MPhA"), National Association of Chain Drug Stores ("NACDS"), National Community Pharmacists Association ("NCPA"), Minnesota Retailers Association ("MnRA"), Minnesota Grocers Association ("MGA"), Astrup Drug, Inc. ("Astrup"), Coborn's, Inc., Falk's Pharmacies, Inc., Genoa Healthcare Minnesota, LLC, Goodrich Pharmacy, Inc., JT Hoeschen, Inc. d.b.a. St. Paul Corner Drug, Setzer Pharmacy, Inc., Thrifty Drug Stores, Inc., Trumm Drug, Inc., Robert Diaz, M.B., a minor, and A.H., a minor, by and through their legal guardian, James Brech (collectively, "Plaintiffs") and as and for their Complaint for Injunctive and Declaratory Relief against Defendants Timothy Pawlenty, not individually, but solely in his capacity as Governor of the State of Minnesota, Cal Ludeman, not individually, but solely in his capacity as the Commissioner of the Minnesota Department of Human Services, Brian Osberg, not individually, but solely in his capacity as Director of the Minnesota Medical Assistance Program, and the Minnesota Department of Human Services ("DHS") (collectively, "Defendants"), state and allege as follows:

INTRODUCTION

1. Plaintiffs bring this action to enjoin an unlawful 5% decrease in the average wholesale price-based reimbursement of single-source drugs by the State of Minnesota Medical Assistance Program ("Medicaid Program"). When Medicaid recipients in Minnesota require prescription medication, participating pharmacies provide the prescribed medications and many other services. The participating pharmacies are subsequently reimbursed through the Medicaid Program, which is managed by the DHS.

2. This unlawful reduction in reimbursements comes from two sources: (1) 2009 State legislation that would increase by 1% the discount applied to the average wholesale price ("AWP"), which is used to determine the rate of reimbursement paid by the Medicaid Program for certain prescription drugs; and (2) the DHS's decision, communicated to providers on August 27, 2009, to adopt a new definition of AWP that reduced reimbursement for drugs whose reimbursement rate is calculated using AWP by, on average, 4%, effective September 26, 2009.[1] (August 27, 2009 Provider Update PRX-09-02 ("August 27, 2009 Provider Update") attached as Exhibit A.) As a result, in many instances pharmacies will be reimbursed *less than their actual cost of providing these medications.* This will necessarily have a dramatic impact upon participating pharmacies and the Medicaid beneficiaries they serve.

3. The Court should grant injunctive relief for the following reasons: (a) the DHS' adoption of the 1% reduction and subsequent September 26, 2009 reimbursement reduction violate Section 1902(a)(30)(A) of the Social Security Act ("Section 30(A)") because the DHS failed to consider the "quality of care" and "access" provisions of Section 30(A); (b) the DHS violated federal law by failing to obtain approval from the United States Department of Health and Humans Services' Centers for Medicare & Medicaid Services ("CMS") before implementing the reimbursement reductions; (c) the DHS has not, and cannot, certify that the reduced reimbursement represents participating

[1] This suit focuses on single-source (i.e., "name brand") drugs, since the reimbursement for multiple-source medications (i.e., generic drugs), although technically subject to the same formula, is capped at "the maximum amount paid by other third-party payors in this state who have maximum allowable cost programs." Minn. Stat. § 256b.0625, subd. 13e(a).

pharmacies' acquisition cost as required by federal law and, indeed, violated federal law by making reimbursement payments lower than Minnesota's estimated acquisition costs; (d) the DHS violated the Minnesota state constitution by adopting reimbursement cuts without legislative authority; (e) the DHS violated its contractual agreement with pharmacy providers by implementing the reimbursement reduction without "establishing" the new reimbursement; and (f) Plaintiffs relied on the previously-established reimbursement and the DHS is therefore obligated to honor it. For these reasons, Plaintiffs are entitled to a declaratory judgment that the reimbursement reductions violate federal and state law and appropriate injunctive relief.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the matter pursuant to 28 U.S.C. § 1331. In addition, the Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367.

5. Venue is appropriate in this District pursuant to 28 U.S.C. § 1391 because the persons sued in their official capacity all maintain offices within this District and the State entities are headquartered within and a substantial part of the events giving rise to these claims occurred in this District.

PARTIES

6. Plaintiff MPhA is an association with over 2,000 members including pharmacies, pharmacists and technicians located throughout the State. MPhA is a professional and trade association whose main purpose is to promote the interests of providers of pharmaceutical services within Minnesota. MPhA also seeks to assure that

patients have access to safe and appropriate care, which includes lobbying and otherwise acting to promote reasonable reimbursement for pharmacy services. Many of MPhA's member pharmacies dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota. MPhA members have standing to bring this action in their own right, the interests at stake are consistent with MPhA's organizational purpose, and neither the relief requested nor the claims asserted require the participation of such members although several are named plaintiffs herein.

7. Plaintiff NACDS is a national association whose members include twenty pharmacy chains in Minnesota with over 650 individual pharmacies within the State. NACDS's mission includes assuring its members are adequately reimbursed by federal and state healthcare programs and assuring patient access to pharmaceutical care. Members of NACDS participate in Minnesota's Medicaid Program.

8. Plaintiff NCPA is a national association whose members include independent community pharmacies and pharmacists including independent community pharmacists in Minnesota. The nation's independent community pharmacists are small business entrepreneurs and multifaceted healthcare providers who represent a vital part of the United States' healthcare delivery system. NCPA's members are acknowledged by consumers as being committed to high quality patient care and services and to restoring, maintaining, and promoting the health and well-being of the general public, including Medicaid patients. NCPA represents the professional and proprietary interests of independent community pharmacists, and promotes and defends those interests, including

those interests pertaining to federal and State healthcare programs. Members of NCPA participate in Minnesota's Medicaid Program.

9. Plaintiff MnRA is a Minnesota retail trade association with its principal place of business in St. Paul, Minnesota. MnRA consists of approximately 2,500 large and small retail stores from across Minnesota. Its membership includes chain pharmacy members that operate approximately 325 pharmacy locations in the State of Minnesota, many of which dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota. MnRA members have standing to bring this action in their own right, the interests at stake are consistent with MnRA's organizational purpose, and neither the relief requested nor the claims asserted require the participation of such members although several are named plaintiffs herein.

10. Plaintiff MGA is a Minnesota trade association with its principal place of business in St. Paul, Minnesota. MGA members include licensed pharmacies in Minnesota that dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota. MGA members have standing to bring this action in their own right, the interests at stake are consistent with MGA's organizational purpose, and neither the relief requested nor the claims asserted require the participation of such members although several are named plaintiffs herein.

11. Plaintiff Astrup is a family-owned corporation organized under the laws of the State of Minnesota with its principal place of business in Austin, Minnesota. Astrup owns and operates twelve licensed pharmacies in rural communities in southern

Minnesota that dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota.

12. Plaintiff Coborn's, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business in St. Cloud, Minnesota. Coborn's operates twenty-three pharmacies in connection with its retail grocery stores throughout central and southern Minnesota. Coborn's dispenses prescription drug products and provides various services to Medicaid beneficiaries in Minnesota and also serves long term care facilities that serve Medicaid beneficiaries.

13. Plaintiff Falk's Pharmacies, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business in Duluth, Minnesota. Falk's operates six pharmacies in north and north central Minnesota, each of which dispenses prescription drugs and provides various services to Medicaid beneficiaries in Minnesota and also serve long term care facilities that serve Medicaid beneficiaries.

14. Plaintiff Genoa is a limited liability company organized under the laws of the State of Oregon with its principal place of business in Auburn, Washington and is qualified to do business in Minnesota. Genoa provides a full array of traditional and non-traditional in-house pharmacy services for community mental health centers throughout the United States, including two centers within Minnesota. Many of the mental health patients Genoa serves are Medicaid beneficiaries.

15. Plaintiff Goodrich Pharmacy, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business in Anoka, Minnesota. Goodrich is an independent community pharmacy that is part of a five pharmacy

community pharmacy group. Goodrich has been locally owned by its practicing pharmacists since 1864. All five of its community pharmacies dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota.

16. Plaintiff J.T. Hoeschen, Inc. d.b.a. St. Paul Corner Drug ("St. Paul Corner Drug") is a Minnesota corporation with its principal place of business in St. Paul, Minnesota. St. Paul Corner Drug dispenses prescription drug products and provides various services to Medicaid beneficiaries in Minnesota and also serves long term care facilities that serve Medicaid beneficiaries.

17. Plaintiff Setzer Pharmacy, Inc. is a Minnesota corporation with its principal place of business in St. Paul, Minnesota. Setzer has been serving Minnesotans since 1956. Setzer is a pharmaceutical care oriented pharmacy that dispenses prescription drug products and provides various services to Medicaid beneficiaries in Minnesota.

18. Plaintiff Thrifty Drug Stores, Inc. is an employee-owned corporation, organized under the laws of the State of Minnesota, with its principal place of business in Maple Grove, Minnesota. Thrifty operates fifty-one pharmacies in Minnesota, approximately half of which serve rural and outstate communities. Thrifty's pharmacies dispense prescription drug products and provide various services to Medicaid beneficiaries in Minnesota and also serve long term care facilities that serve Medicaid beneficiaries.

19. Plaintiff Trumm Drug, Inc. is a corporation organized under the laws of the State of Minnesota with its principal place of business in Alexandria, Minnesota. It is a family-owned, third generation business that has been in business for fifty-eight years.

Trumm Drug operates six pharmacies in central and northern Minnesota that dispense prescription drug products and provide various services to Medicaid beneficiaries.

20. Plaintiff Robert Diaz is a Minnesota resident residing in Glenville, Minnesota. Mr. Diaz is a Medicaid beneficiary.

21. Plaintiffs M.B. and A.H. are minors who are Minnesota residents residing with their legal guardian, James Brech, in Albert Lea, Minnesota. M.B. and A.H. are Medicaid beneficiaries.

22. Defendant Timothy Pawlenty is named solely in his official capacity as Governor of the State of Minnesota. As Governor, Mr. Pawlenty has executive responsibility for the DHS, the state agency with primary responsibility for administering the Medicaid Program in Minnesota. Minn. Stat. § 245.03 (2008).

23. Defendant Cal Ludeman is named solely in his capacity as Commissioner of the DHS. The DHS is charged with administering the Medicaid Program in Minnesota and publicized the August 27, 2009 Provider Update. (Exhibit A.)

24. Defendant Brian Osberg is named solely in his capacity as the Director of the DHS's Medicaid Program.

25. Defendant DHS is sued in its capacity as the primary department charged with administering the Medicaid Program in Minnesota and implementing the 1% and 4% reductions in reimbursement. It is the agency that publicized the August 27, 2009 Provider Update. (*Id.*)

The Medicaid Program.

26. Medicaid is a joint federal and state program created under Title XIX of the Social Security Act to provide health care to indigent and otherwise disadvantaged Americans. Federal and state government agencies share responsibility for funding the Medicaid Program. Each state administers its respective Medicaid program in accordance with federal and state law and a Medicaid State Plan which CMS reviews and approves.

27. The Minnesota Medicaid State Plan ("State Plan") is the DHS's comprehensive written statement submitted to CMS that describes the nature and scope of the State Medicaid Program and give assurance that DHS will administer the State Plan in conformity with the specific requirements of the Social Security Act. CMS must approve all amendments to a state plan before a state may implement "material changes." 42 C.F.R. § 430.12(c)(1)(i) and (ii). In addition, a state must give public notice of changes in state-wide methods and standards for setting reimbursement. 42 C.F.R. § 447.20.

28. In order to comply with federal law, a state Medicaid program must comply with the "quality of care" requirement of Section 30(A), which provides in pertinent part:

> (a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments are consistent with efficiency, economy, and quality of care....

42 U.S.C. § 1396a(a)(30)(A).

29. A state Medicaid program must also comply with the "access" clause of Section 30(A), which provides in pertinent part:

> (a) A state plan for medical assistance must . . . provide such methods and procedures relating to the utilization of, and payment for, care and services available under the plan . . . as may be necessary . . . to assure that payments are . . . sufficient to enlist enough providers so that care and services are available under the plan as least to the extent that such care and services are available to the general population in the geographic area.

Id.

30. For that reason, federal regulations require the DHS to offer payments to providers "sufficient to enlist enough providers so that services under the plan are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204.

31. Therefore, to demonstrate that reimbursement complies with federal statutes, federal regulations, and the State Plan, and that its reimbursement is not arbitrary and capricious, a State must show that it has evaluated, prior to implementation of new rates and methodologies, that the proposed reimbursement complies with the "quality of care" and "access" provisions of Section 30(A), and will ensure enough providers are enlisted so that services under the plan are available to recipients at least to the extent that they are available to the general public.

The Method Used to Calculate Minnesota's Medicaid Reimbursement.

32. Retail pharmacies that take part in the Medicaid Program dispense prescription drugs and provide related services to patients who are covered by Medicaid. In return, those retail pharmacies apply for, and receive, reimbursements from DHS.

33. Reimbursement paid to Medicaid-enrolled pharmacies for drug products and services contains two components: (1) a reasonable dispensing fee meant to compensate a pharmacy for the dispensing costs that it incurs and the associated services it provides, and (2) reimbursement for the drug product itself.[2]

34. With regard to the first component of reimbursement, Minnesota does not provide a reasonable dispensing fee that compensates participating pharmacies for the costs that they incur and the related services that they provide.

35. With regard to the second component, under Minnesota law, Minnesota Medicaid reimbursement for prescription drugs cannot exceed the lowest of three amounts. They are: (1) the actual acquisition costs ("AAC") of the drugs plus a fixed dispensing fee; (2) the maximum allowable cost set by the federal government or by the Commissioner of the DHS plus a fixed dispensing fee; (3) or the usual and customary price charged to the public. Minn. Stat. § 256B.0625 subd. 13e(a). As of July 2008, AAC was directed to be "estimated by the Commissioner at average wholesale price minus 14 percent." *Id.*

The AWP Reductions.

36. The July 1, 2008 state amendment that established the actual acquisition cost at AWP minus 14% was approved on March 18, 2009. *Id.*

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[2] A reimbursement rate for each individual drug product is set for, and corresponds to, the National Drug Code ("NDC") for that drug product. A NDC is a unique numerical code that identifies the manufacturer, active ingredients, dosage, size, and packaging for a drug product.

37. On May 14, 2009, the Minnesota legislature passed and the Governor signed into law HF 1362, 2009 Minn. Chapter Law 79, which increased the discount to AWP, thereby establishing AAC at AWP minus 15%, as of July 1, 2009.

38. On August 27, 2009, the DHS issued the August 27, 2009 Provider Update, which, among other things, indicates that the change to AWP minus 15% has already been implemented. (Exhibit A.)

39. The August 27, 2009 Provider Update also informed participating pharmacies that, due to a class action settlement entered into in Massachusetts, reimbursements will be further reduced by, on average, 4% as of September 26, 2009. (*Id.*)

40. First DataBank, Inc., a clearinghouse of data pertaining to the pharmaceutical industry, publishes lists of prescription drugs and the AWP for each prescription drug. The DHS uses First DataBank data in calculating AAC.

41. On March 17, 2009, First DataBank entered into a class action settlement agreement ("First DataBank Settlement") in which it agreed to reduce the mark-up to the wholesale average cost ("WAC") from 1.25 to 1.20 when setting AWPs for 1,442 NDCs. In addition, First DataBank announced it would voluntarily cut the WAC mark-up to 1.20 when setting AWPs for thousands of NDCs where the mark-up exceeded 1.20. In effect, First DataBank agreed to reduce its listed AWP for virtually all NDCs by, on average, 4%. These reductions of AWPs occurred on September 26, 2009.

42. The practical effect of First DataBank's reduction of the mark-up to WAC when setting AWPs is that the reimbursement for drug products tied to AWP has been reduced further by slightly more than 4%.

43. In addition, Minnesota collects a 2% tax on gross revenues of drug wholesalers. This tax is passed through by wholesalers to pharmacies which purchase the drug products. Minn. Stat. § 295.52.

The Department Has Failed To Comply With Federal And State Law.

44. There is nothing in the administrative record that suggests that the DHS considered or otherwise took into account either the "quality of care" or the "access" provisions of Section 30(A) prior to implementing these reductions in the reimbursement rate.

45. Indeed, Plaintiffs have not found any evidence that the DHS took any steps to determine how the reimbursement reductions would affect compliance with the "quality of care" or "access" provisions of Section 30(A).

46. In addition, there is no indication that Defendants sought or received approval from CMS for a State Plan amendment that would allow either for this reduction in actual reimbursement to pharmacies, or in the commensurate reduction in care quality or access.

47. The State must amend its State Plan before implementing "material changes," including those made to "reflect . . . court decisions" such as the First DataBank settlement. 42 C.F.R. §430.12(c)(1)(i) and (ii). There is no evidence it did so for either reduction or received CMS approval for them.

48. There is no evidence that the new, reduced reimbursement payments were "designed to enlist participation" of sufficient providers of Medicaid services, as the DHS warranted in the State Plan.

49. The DHS has not made, and cannot make, the required analysis or findings that the new reduced reimbursement payments properly reflect the estimated acquisition costs (referred to as "AAC" by Minnesota) for prescription drugs in the State of Minnesota. As a result, Minnesota has not made proper assurances to CMS that either the 1% reimbursement reduction or the reimbursement reduction that went into effect on September 26, 2009 represents its best estimate of estimated acquisition cost as required by federal law. 42 C.F.R. § 447.518.

50. Minnesota also has not properly certified to the federal government in its State Plan that the 1% reimbursement reduction and the reduced reimbursement as of September 26, 2009 is "designed to enlist participation of a sufficient number of providers in the program so that eligible persons can receive the medical care and services included in the plan at least to the extent these are available to the general population."

Harm To Medicaid Beneficiaries and Participating Pharmacies.

51. Unless enjoined, the effect of the reimbursement reductions will be catastrophic for Medicaid beneficiaries across Minnesota, as well as health service providers like the participating pharmacies. The 1% reimbursement reduction and subsequent 4% reduction will result in the reimbursement for many drugs at a level below participating pharmacies' break even cost.

52. Participating pharmacies will be forced to take drastic steps if the reimbursement reductions go into effect, including ceasing to fill Medicaid prescriptions and dropping their enrollment in the Medicaid Program. This, in turn, will result in reduced access to thousands of Medicaid recipients across Minnesota.

53. Many of the State's most vulnerable citizens, including many mental health patients who receive treatment at community mental health centers, will be hard hit by the reduction in reimbursement.

54. This population is particularly vulnerable to medication compliance problems. For example, medical management of schizophrenia through use of Clozapine requires regular blood tests to monitor for a life-threatening side effect. Those tests must be logged in a register mandated by the United States Food and Drug Administration. These, and many other critical services, will be jeopardized by the reductions in reimbursement.

55. On July 30, 2009, MPhA discussed the pending reimbursement reductions with DHS representatives. MPhA informed the State that implementing the reduced reimbursement would pose serious access and quality issues in the Minnesota Medicaid Program.

56. On August 26, 2009, MPhA held another meeting with representatives of the DHS, and were informed that, despite not having undertaken any study on the effect the reimbursement reductions would have on access and quality, the DHS had decided to implement the rate cuts.

57. On August 28, 2009, MPhA members were informed of the DHS's decision not to address the access and quality issues posed by the drastic reimbursement reductions.

58. On September 18, 2009, MPhA President Bruce Thompson met with a representative of the Governor to explain, once again, the impending crisis of access and quality of care for Medicaid beneficiaries.

59. Plaintiffs made every effort, including bringing pharmacy owners to meetings, to alert the DHS and the Governor's office to the detrimental effects of the reimbursement reductions on actual patient access and quality of care. Plaintiffs regard this lawsuit as a last resort which they sought to avoid. The Governor's office and the DHS have left Plaintiffs with no choice but to sue and seek injunctive relief.

60. In short, there is a real and immediate risk of harm to participating pharmacies and Medicaid beneficiaries due to the 1% and 4% reductions in reimbursement.

COUNT I
Violation Of 42 U.S.C. § 1983

61. Plaintiffs incorporate Paragraphs 1 – 60 as if set forth fully here.

62. An actual controversy exists between the parties concerning whether Minnesota violated the participating pharmacies and Medicaid beneficiaries rights pursuant to 42 U.S.C. § 1983.

63. Plaintiffs have a recognized private right of action to enforce the quality and equal access provisions of Section 30(A).

WHEREFORE, Plaintiffs respectfully request that this Court enter an order declaring the July 1, 2009 and September 26, 2009 reimbursement reductions invalid and granting Plaintiffs their attorneys' fees and costs.

COUNT II
Injunction Halting The July 1, 2009 Rate Cut

64. Plaintiffs incorporate Paragraphs 1 – 63 as if set forth fully here.

65. Pursuant to Section 30(A), the State had a duty to consider efficiency, economy, quality, and access when establishing reimbursement rates. It is the State's obligation to develop methods and procedures for assuring that it complies with Section 30(A). Here, the DHS violated the Supremacy Clause of the United States Constitution by implementing the reimbursement reductions because it has failed to consider or give sufficient weight to the impact of the rate reduction on quality of care or access to care for Medicaid beneficiaries required by Section 30(A), including the relationship of the reimbursement payments to provider costs. Additionally, there is no evidence that the DHS has complied with the requirements of Section 30(A) prior to implementing the reimbursement reductions. Finally, it is evident that the new reimbursement rates will directly result in a failure of the State to comply with the requirements of Section 30(A) because reimbursement will not be sufficient to assure "quality of care" and access.

66. Moreover, there is no evidence that the DHS has complied with the requirements of federal law or to obtain approval of a State Plan amendment prior to implementing reimbursement reductions. Further, there is no evidence that the DHS has complied with state law requirements that it obtain approval for an amendment to the

State Plan prior to implementing it or that it made arrangements to obtain or retain such approval of the State Plan.

67. There is no evidence that the DHS determined that estimated acquisition costs went down, on average, 1% on July 1, 2009 and no evidence that the DHS represented to CMS that this occurred.

68. In short, the DHS acted arbitrarily and capriciously, unlawfully and in violation of the Supremacy Clause of the United States Constitution when it implemented the July 1, 2009 reimbursement reduction. Based on the foregoing, Plaintiffs are likely to succeed on the merits.

69. Irreparable harm will occur if the rate cut goes into effect because the members of MPhA, NACDS, NCPA, MnRA, and MGA, and the other Plaintiff-Pharmacies in this matter will be forced to reduce levels of services, deny prescriptions to new Medicaid beneficiaries, shut down, reduce service hours, and/or refuse to participate in the Medicaid Program and provide services to Medicaid beneficiaries. Plaintiffs have no administrative remedy, nor any plain, speedy, or adequate remedy except by this complaint for injunctive relief.

70. The balance of harms favors entering the injunction because the physical and emotional harm suffered by Medicaid beneficiaries deprived of needed access to quality pharmaceutical products if the reimbursement reduction remains in effect, as well as the inevitable loss of employment if participating pharmacies are forced to close or lay off workers, outweighs little if any monetary loss to the State. Moreover, the State is

receiving additional federal funding, the express purpose of which is to avoid this type of cut.

71. It is in the public interest that the Court grant the injunction because it is always in the public interest that state governments comply with federal and state law. Moreover, it is in the public interest to assure that participating pharmacies can continue to serve Medicaid beneficiaries.

WHEREFORE, Plaintiffs respectfully request that this Court enter an injunction enjoining the rate cut set forth in 2009 Minn. Chapter Law 79.

COUNT III
Injunction Halting The September 26, 2009 Rate Cut

72. Plaintiffs incorporate Paragraphs 1 – 71 as if set forth fully here.

73. Pursuant to Section 30(A), the State had a duty to consider efficiency, economy, quality, and access when implementing reimbursement rates. It is the State's obligation to develop methods and procedures for assuring that it complies with Section 30(A). Here, the DHS violated the Supremacy Clause of the United States Constitution by implementing the reimbursement reductions because it has failed to consider or give sufficient weight to the impact of the rate reduction on quality of care or access to care for Medicaid beneficiaries required by Section 30(A), including the relationship of the reimbursement payments to provider costs. Additionally, there is no evidence that the DHS has complied with the requirements of Section 30(A) prior to implementing the reimbursement reductions. Finally, it is evident that the new reimbursement rates will

directly result in a failure of the State to comply with the requirements of Section 30(A) because reimbursement will not be sufficient to assure "quality of care" and access.

74. Moreover, there is no evidence that the DHS has complied with the requirements of federal law or to obtain approval of a State Plan amendment prior to implementing reimbursement reductions. Further, there is no evidence that the DHS has complied with state law requirements that it obtain approval for an amendment to the State Plan prior to implementing it or that it made arrangements to obtain or retain such approval of the State Plan.

75. There is no evidence that the DHS determined that estimated acquisition costs went down, on average, 4% on September 26, 2009 and no evidence that the DHS represented to CMS that this occurred.

76. In short, the DHS acted arbitrarily and capriciously, unlawfully and in violation of the Supremacy Clause of the United States Constitution when it adopted the September 26, 2009 reimbursement reduction. Based on the foregoing violations, Plaintiffs have a likelihood of success on the merits.

77. Irreparable harm will occur if the rate cut goes into effect because the members of MPhA, NACDS, NCPA, MnRA, and MGA, and the other Plaintiff-Pharmacies in this matter will be forced to reduce levels of services, deny prescriptions to new Medicaid beneficiaries, shut down, reduce service hours, and/or refuse to participate in the Medicaid Program and provide services to Medicaid beneficiaries. Plaintiffs have no administrative remedy, nor any plain, speedy, or adequate remedy except by this complaint for injunctive relief.

78. The balance of harms favors entering the injunction because the physical and emotional harm suffered by Medicaid beneficiaries deprived of necessary access to quality pharmaceutical products if the reimbursement reduction remain in place, as well as the inevitable loss of employment if participating pharmacies are forced to close or lay off workers, outweighs little, if any, monetary loss to the State. Indeed, the State is receiving additional federal funding, the express purpose of which is to avoid this type of cut, so it is not apparent that Defendants will suffer any harm if the injunction is granted.

79. It is in the public interest that the Court grant the injunction because it is always in the public interest that state governments comply with federal and state law. Moreover, it is in the public interest to assure that participating pharmacies can continue to serve Medicaid beneficiaries.

WHEREFORE, Plaintiffs respectfully request that this Court enter an injunction enjoining the September 26, 2009 reimbursement reduction.

COUNT IV
Declaratory Judgment That The July 1, 2009 Rate Cut Violates Federal Law

80. Plaintiffs incorporate Paragraphs 1 – 79 as if fully set forth here.

81. An actual controversy exists between the parties concerning whether the reimbursement reduction implemented by the DHS on July 1, 2009 violates federal law.

82. For the reasons set forth above, the July 1, 2009 rate cut violates federal law.

83. Moreover, the rate cut is preempted by Section 30(A) of the Social Security Act.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the rate cut set forth in 2009 Minn. Chapter Law 79 null and void.

COUNT V
Declaratory Judgment That The September 26, 2009 Rate Cut Violates Federal Law

84. Plaintiffs incorporate Paragraphs 1 – 83 as if fully set forth here.

85. An actual controversy exists between the parties concerning whether the rate cut implemented by the DHS on September 26, 2009 violates federal law.

86. For the reasons set forth above, the September 26, 2009 rate cut violates federal law.

87. Moreover, the rate cut is preempted by Section 30(A) of the Social Security Act.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the reimbursement reduction set forth in the August 27, 2009 Provider Update null and void.

COUNT VI
Declaratory Judgment That the September 26, 2009 Rate Cut Violates Minnesota Law

88. Plaintiffs incorporate Paragraphs 1 – 87 as if fully set forth here.

89. The Provider Agreement is uniform among participating pharmacies and other MPhA, NACDS, NCPA, MnRA, and MGA members.

90. The Provider Agreement requires the DHS to "establish" schedules of reimbursement.

91. By failing to take any steps to consider or legally implement the rate cut referenced in the Provider Update, the DHS breached the terms of the Provider Agreement.

92. For the reasons set forth above, the September 26, 2009 rate cut violates state law.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the reimbursement reduction set forth in the Provider Update null and void.

COUNT VII
Declaratory Judgment That the July 1, 2009 Rate Cut Violates Minnesota Law

93. Plaintiffs incorporate Paragraphs 1 – 92 as if fully set forth here.

94. The Provider Agreement is uniform among participating pharmacies and other MPhA, NACDS, NCPA, MnRA, and MGA members.

95. The Provider Agreement requires the DHS to "establish" schedules of reimbursement.

96. By failing to obtain approval from CMS before implementing the July 1, 2009 rate cut, the DHS breached the terms of the Provider Agreement.

97. The Minnesota Constitution, Art. I, Sec. 11, prohibits the Minnesota legislature from enacting legislation that changes the terms of contracts with private parties.

98. 2009 Minn. Chapter Law 79 purports to enact a 1% rate cut on providers as of July 1, 2009.

99. The reimbursement reduction implemented on July 1, 2009, has not yet been approved by CMS.

100. By failing to complete the process required to legally establish a reimbursement rate under federal law, the DHS failed to "establish" the reimbursement rate, as required in the Provider Agreement.

101. Because the DHS did not complete the process required to lawfully establish a reimbursement rate under federal law before implement the 1% rate cut, 2009 Minn. Chapter Law 79 violates the Minnesota State Constitution.

102. For the reasons set forth above, the July 1, 2009 rate cut violates state law.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the rate cut set forth in 2009 Minn. Chapter Law 79 null and void.

COUNT VIII
Declaratory Judgment That the September 26, 2009 Rate Cut Violates Minnesota Law

103. Plaintiffs incorporate Paragraphs 1 – 102 as if fully set forth here.

104. The Minnesota Constitution requires that all monies paid out of the state treasury be done so pursuant to the appropriate legislation. Article XI, Sec. 1.

105. Prior to the August 27, 2009 Provider Update, material changes to the reimbursement rate had been established through legislation.

106. The DHS's August 27, 2009 Provider Update purports to materially change the reimbursement rate without legislative approval.

107. The DHS is part of the executive branch of the Minnesota state government.

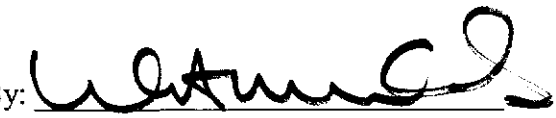
108. By assuming for itself powers exclusively granted to the legislature, the DHS violated the Separation of Powers clause of the Minnesota state constitution. Art. III, Sec. 1.

109. For the reasons set forth above, the September 26, 2009 rate cut violates state law.

WHEREFORE, Plaintiffs respectfully request that this Court enter a judgment declaring the rate cut set forth in the Provider Update null and void.

Dated: October 2, 2009

WINTHROP & WEINSTINE, PA

By: 

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MHCP Enrolled Providers

MHCP Provider Update PRX-09-02

First DataBank, Medi-Span, and McKesson AWP Litigation Settlements

August 27, 2009

Pharmacy Reimbursements May Be Impacted by Upcoming Reporting Change

Minnesota Health Care Programs (MHCP) uses the Blue Book Average Wholesale Price (AWP) published by First DataBank to calculate the Estimated Acquisition Cost (EAC) for fee-for-service pharmacy claim reimbursement. The current formula is AWP-15%. Effective September 26, 2009, First DataBank is expected to adjust its reporting of the Blue Book AWP for certain prescription drugs by adding 20% to Wholesale Acquisition Cost (WAC) for all products that currently have a WAC to AWP spread in excess of 20%. Your MHCP reimbursement may be impacted by this reporting change.

Background

On March 30, 2009, the U.S. District court for the District of Massachusetts entered a Final Order and Judgment approving a long-awaited class action settlement that involved two major publishers of drug pricing information, First DataBank and Medi-Span. The lawsuit alleged that AWP indices were not based on a survey of wholesalers as claimed and that the WAC-to-AWP spread was arbitrarily raised from 20% to 25% on more than 400 brand-name drugs beginning in 2002. The suit alleged that only one wholesaler (McKesson Corporation) was surveyed. Historically, the AWP was calculated by adding 20% to WAC, a price set by drug manufacturers.

Settlement Provisions and Additional Reporting Changes

First DataBank and Medi-Span agreed to:

- "Rollback" to WAC-to-AWP spread from 25% to 20% for all National Drug Codes (NDCs) for which AWP is set based upon a WAC or Direct Price markup in excess of 1.20. The rollback may include NDCs for drugs that were not included in the lawsuit. This change is scheduled to occur on September 26, 2009
- Cease publishing AWP data no later than two years following the date that the AWP adjustments noted above are implemented

Impacts

The pharmacy reimbursement rate of AWP minus 15% plus $3.65 is set in Minnesota law. MHCP will continue to reimburse pharmacies at AWP minus 15% using the revised AWP values. Any change in the methodology of reimbursement for prescriptions will require action by the Minnesota Legislature and approval by the Governor.

Additional Resources

- Minnesota Statute 256b.0625 subd.13e
- First DataBank AWP Communications

Sign up to receive Provider Updates and other MHCP notices in your e-mail account.